

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/006745

International filing date (day/month/year)
02.03.2005

Priority date (day/month/year)
08.03.2004

International Patent Classification (IPC) or both national classification and IPC
C11C3/10, A23D9/007, A23D9/02, A23L1/30, A61K31/575

Applicant
BUNGE OILS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-28 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-28 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-28 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

Novelty

It is known from the prior art that medium-chain triglyceride oils and/or phytosterols improve plasma lipid profile and cardiovascular risk (see XP-2331081, or XP-2331083).

However a composition comprising interesterified lipids (as defined in claim 1) and phytosterols, in concentration ranges as defined in claim 1, and the related method claims (and related dependent claims) are new over the available prior art.

Inventive step

Publication XP-2331081 is about a functional oil, which improves the plasma lipid profile in men. It is considered to represent a close state of the art.

That document discloses a composition with about 70 % MCT, 30% LCT and about 3,4% of added phytosterols. However, the medium- and long chain triglycerides are not interesterified, and the quantity of phytosterols is lower than in the present claims. The prior art does not provide any clear and unambiguous teaching for the skilled person to interesterify the MCT with the LCT in said publication and to increase the quantity of the phytosterols to a level of 4 to 20 %.

Another relevant document of the prior art is US 6117475. It is about fat based food products comprising phytosterols and their beneficial effects (blood cholesterol lowering effect). It discloses a composition comprising interestified fat (palm oil [LCT] and palm kernel oil [MCT]) and phytosterols or phytosterol-ester (approx. at 16 %), see example VIII. However the interesterified lipid represents significantly less than 80% of the lipids in the preparation of example VIII, and there is no clear and unambiguous teaching for the skilled person to increase that lipid to at least 80% (of the lipid content).

Since no other document of the prior art discloses in a clear and unambiguous way the presently claimed composition or the method of producing it, an inventive step is acknowledged for all claims.

3 Other

- 3.1 Claims 2, 3, 23 and 24 are defined by a result-to-be-achieved. However, it is not clear how that result is achieved: For example for how long, and how much of said lipid is to be consumed in order to achieve the claimed result?

The quantity and the duration are considered essential parts of a method claim defined by a result-to-be achieved, and consequently should form part of such claims.

- 3.2 Some National Patent Offices, such as the EPO, will object to product-type claims (such as claims 2 and 3) defined by a function. Product-type claims should be defined by product features only.

A similar objection is raised for a product claim defined by a use (see claim 15).

If a function is to be claimed, then a method-type claim should be used, for example: "method for [function] characterized by [method steps]".

If a use is to be claimed, then a use-type of claim should be formulated.

In case amendments are filed, Art. 41 (2) PCT has to be observed.